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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,665	06/12/2001	Douglas R. Daum	279.358US1	4223

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EXAMINER	
OROPEZA, FRANCES P	
ART UNIT	**PAPER NUMBER**
3762	18

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/879,665	DAUM, DOUGLAS R.	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-17 and 19-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-17 and 19-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *16*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *17* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 1/26/04 has been entered.

Response to Amendment

2. The Applicant's has amended claims 1, 3-17 and 19-30 to overcome the prior art of record, hence a new grounds of rejection is established for claims 1, 3-17 and 19-30 in the subsequent paragraphs.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner is unable to find in the specification of the detecting the thoracic impedance

"across a plurality of blood vessels" and "net fluid shift away from the thorax". These limitations appear to be new matter and new matter may not be entered at this point in the prosecution.

5. Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner is unable to find in the specification of the detecting the thoracic impedance "across a plurality of blood vessels" and "net fluid shift away from the thorax", nor discussion of the apparatus and processes to support these limitations. Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. Claims 1, 3, 4, 8-17, 19, 20 and 23-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al. (US 6044297) in view of Pitts Crick et al. (US 6104949) and further in view of Hudrlik (US 5282840).

Sheldon et al. disclose an implantable stimulation device and teach a responsive hypotension detection detection indicator, to indicate both postural (col. 7 @ 28) and non-postural (col. 7 @ 44) hypotension, using activity sensors and heart rate sensors for the purpose of providing treatment to prevent the patient from fainting or feeling faint (col. 5@ 42-46; col. 6 @ 53-65; col. 7 @ 27-59; col. 9 @ 10-13). The activity sensors can define posture and activity

levels and both types of posture and activity signals can be used to affect the therapy by controlling the pacing rate delivered by the pacemaker (col. 1 @ 19-45). Sheldon et al. teach inclusion of blood pressure monitoring, read as monitoring of hypotension, to treat syncopal patients (col. 9 @ 10-13; col. 12 @ 10-31; col. 22 @ 4-9).

As to the stepping of rate responsive factor (claims 14-16 and 27-30), pacing therapy is taught as being stepped (col. 7 @ 31-34; col. 11 @ 63 – col. 12 @ 9). US 5354317 to Alt, incorporated by reference (col. 2 @ 51-53; col. 3 @ 7-17), discloses variable rate pacing to provide electrical output signals uniquely responsive to pre-selected positions, including gradual rate changes (Alt - abstract) to provide optimal pacing therapy for the subject's specific needs.

Sheldon et al. disclose the claimed invention except for using transthoracic impedance to indicate hypotension.

Postural hypotension (fluid moving to the patient's extremities and the patient being unable to compensate for this movement) and pulmonary edema (lungs filling with fluid and the patient being unable to compensate for this fluid collection) are recognized as conditions frequently associated with the later stages heart failure (Sheldon et al. – col. 7 @ 31-46; Pitts Crick et al. – col. 4 @ 48 – col. 5 @ 55; col. 5 @ 37-39; col. 6 @ 20-30). Both these conditions create changes in the fluid levels in the thoracic tissues as fluid is shifted away from the thorax in the hypotension condition and as fluid is shifted into the throrax in the edema condition, hence accurate monitoring of fluid changes in the trans-thoracic tissues can quantify

changes associated with the conditions of hypotension and pulmonary edema and can indicate the need for treatment (Sheldon et al. – col. 7 @ 31-46; col. 21 @ 62 – col. 22 @ 9; Pitts Crick et al. – abstract; col. 1 @ 38-45; col. 2 @ 35-40; col. 5 @ 34-39; col. 6 @ 20-30). Pitts Creek et al. teach the monitoring of fluid changes using the sensing of trans-thoracic impedance for the purpose of accurately monitoring the fluid level in the tissues, and correlating posture changes with impedance to diagnose and treat congestive heart failure.

In the 09/832,365 application that is incorporated by reference in the instant applcation, the Applicant states treatment of hypotension can be based on trans-thoracic impedance and one or more secondary variables such as an accelerator to detect posture changes (specification – page 10, lines 15-19), hence absent any teaching of criticality or unexpected results, merely changing the basis for treatment of hypotension from an impedance sensor to an impedance and activity sensors would have been an obvious design choice.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used trans-thoracic impedance sensors with posture sensors to monitor fluid changes in the Sheldon et al. system in order to utilize a proven means to measure shifts in thoracic fluids so automatic treatment is provided that rapidly responds to the early signs of fluid shifts in the thorax (col. 1 @ 40-46; col. 5 @ 34-39; col. 6 @ 20-30).

Modified Sheldon et al. disclose the claimed invention except for:

- the responsive hypotension indicator being responsive to thoracic impedance, indicating a fluid shift away form the thorax (claims 1 and 17),

- a respiration sensor used as a first sensor to define metabolic rate and to provide a base rate for pacing (claims 1 and 17), and
- a rate responsive factor, being adjusted in response to the hypotension condition indicator (the thoracic impedance signal), the rate responsive factor impacting the pacing rate (claims 1 and 17).

Hudrlik discloses an implantable stimulation device to manage fluid flow and teaches that gross tissue insults, created by a significant reduction of blood flow to tissue of the thorax, cause dramatic, net shifts in the impedance (col. 2 @ 32-35). These fluid shifts are treated by increased pacing rates (col. 11 @ 30-43) for the purpose of assisting in shifting the fluid back to the thorax (col. 2 @ 32-39). Hudrlik teaches using throacic impedance (the responsive hypotension indicator), respiratory (first sensor) and activity monitors to define the pacing treatment in situations of fluid shifts (col. 3 @ 9-15). The pacing rate is established based on the first sensor (respiration sensor) and adjusted using a rate responsive factor (having an instantaneous and long-term component) that is based on the hypotension indicator (impedance sensor) (col. 3 @ 9-27; col. 3 @ 59 – col. 4 @ 1; col. 6 @ 3-22; col. 10 @ 51 – col. 11 @ 18; col. 11 @ 30-43; col. 11 @ 55 – col. 12 @ 27; col. 12 @ 59-67). The impedance measurement includes a plurality of blood vessels (col. 4 @ 45-54). As discussed previously, hypotension is recognized as being associated with a fluid shift to the extremities causing fainting or the feeling of being faint. The fluid shift associated with hypotension is read a significant reduction of blood flow in the thorax. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used thoracic impedance, respiratory and activity sensors to

monitor fluid shifts and to increase the pacing rate as needed to shift fluid back to the thorax based on the first sensor and the rate responsive factor in the modified Sheldon et al. system in order to utilize proven monitoring and treatment system for fluid shifts so adequate fluid flow is provided to the thoracic tissue avoiding tissue damage (ischemia) and preventing patient injury from falls that might result if the patient faints (col. 2 @ 32-39).

7. Claims 5-7, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al. (US 6044297) in view of Pitts Crick et al. (US 6104949) and further in view of Hudrlik (US 5282840) and further in view of Combs et al. (US 5957861). As discussed in paragraph 6 of this action, modified Sheldon et al. disclose the claimed invention except for the cutoff frequency for the fluid impedance signal being 0.01 to 0.5 Hz, or approximately 0.1 Hz.

Combs et al. teach measure the impedance of fluid using a measurement frequency range of 0.01 to 0.5 Hz, or approximately 0.1 Hz for the purpose of removing cardiac and respiratory components from the impedance signal. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an impedance measurement frequency range of 0.01 to 0.5 Hz, or approximately 0.1 Hz in the modified Shelson et al. system in order to avoid extraneous noise in the fluid impedance signal so an accurate determination of the fluid level can be determined (col. 6 @ 58 – col. 7 @ 33).

8. Claims 1, 3, 8-10, 13, 17, 19, 20, 23-26 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferek-Petric et al. (US 5913879) in view of Standberg (EP 0 620 420 A1) and further in view of Hudrlik (US 5282840).

Ferek-Petric et al. teach an implantable therapy device that detects venous pooling (correlative to hypotension), read as detecting fluid shift away from the thorax, using a flow detector and provides therapy in response to the fluid shift (abstract; figure 2; col. 1 @ 7-11; col. 3 @ 17-63). Ferek-Petric et al. teach blood flow measurement can be made by impedance measurements (col. 2 @ 51-55) as taught by Strandberg using electrodes (col. 5 @ 11 – col. 6 @ 4).

Ferek-Petric et al. disclose the claimed invention except for:

- the responsive hypotension indicator being responsive to thoracic impedance, indicating a net shift in fluid shift away form the thorax across a plurality of vessels (claims 1 and 17) ,
- a respiration sensor used as a first sensor to define metabolic rate and to provide a base rate for pacing (claims 1 and 17),
- a rate responsive factor, being adjusted in response to the hypotension condition indicator (the thoracic impedance signal), the rate responsive factor impacting the pacing rate (claims 1 and 17), and
- a sensor correlative to the subject's metabolic need (claims 1 and 17), the signal being a breathing signal (claims 8 and 24) or an accelerometer (claim 25).

Hudrlik discloses an implantable stimulation device to manage fluid flow and teaches that gross tissue insults, created by a significant reduction of blood flow to tissue of the thorax, cause dramatic, net shifts in the impedance (col. 2 @ 32-35). These fluid shifts are treated by

increased pacing rates (col. 11 @ 30-43) for the purpose of assisting in shifting the fluid back to the thorax (col. 2 @ 32-39). Hudrlik teaches thoracic impedance (the responsive hypotension indicator), respiratory (first sensor) and activity monitors are used to define the pacing treatment in situations of fluid shifts (col. 3 @ 9-15). The pacing is established based on the first sensor (respiration sensor) and adjusted using a rate responsive factor (have an instantaneous and long-term component) based on the hypotension indicator (impedance sensor) (col. 3 @ 9-27; col. 3 @ 59 – col. 4 @ 1; col. 6 @ 3-22; col. 10 @ 51 – col. 11 @ 18; col. 11 @ 30-43; col. 11 @ 55 – col. 12 @ 27; col. 12 @ 59-67). The impedance measurement includes a plurality of blood vessels (col. 4 @ 45-54). As discussed previously, hypotension is recognized as being associated with a fluid shift to the extremities causing fainting or the feeling of being faint. The fluid shift associated with hypotension is read a significant reduction of blood flow in the thorax. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used thoracic impedance, respiratory and activity sensors to monitor fluid shifts and to increase the pacing rate as needed to shift fluid back to the thorax based on the first sensor and the rate responsive factor in the modified Sheldon et al. system in order to utilize proven monitoring and treatment system for fluid shifts so adequate fluid flow is provided to the thoracic tissue avoiding tissue damage (ischemia) and preventing patient injury from falls that might result if the patient faints (col. 2 @ 32-39).

9. Claims 4-7, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferek-Petric et al. (US 5913879) in view of Standberg (EP 0 620 420 A1) and further in view of Hudrlik (US 5282840) and further in view of Combs et al. (US 5957861). As discussed in

paragraph 8 of this action, modified Ferek-Petric et al. disclose the claimed invention except for the cutoff frequency for the fluid impedance signal being 0.01 to 0.5 Hz, or approximately 0.1 Hz to reflect baseline changes.

Combs et al. teach measure the impedance of fluid using a measurement frequency range of 0.01 to 0.5 Hz, or approximately 0.1 Hz for the purpose of removing cardiac and respiratory components from the impedance signal so baseline changes can be detected. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an impedance measurement frequency range of 0.01 to 0.5 Hz, or approximately 0.1 Hz in the modified Ferek-Petric et al. system in order to avoid extraneous noise in the fluid impedance signal so an accurate determination of the fluid level can be determined (col. 6 @ 58 – col. 7 @ 33).

Specification

10. The amendment filed 1/26/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The Examiner is unable to find in the specification of the detecting the thoracic impedance "across a plurality of blood vessels" and "net fluid shift away from the thorax".

Applicant is required to cancel the new matter in the reply to this Office Action.

Statutory Basis

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
2/21/04

Angela D Sykes

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